

Subject: Whistleblower letter
From: Brad Racino <bradracino@inewsource.org>
Date: 8/12/19, 11:06 AM
To: "Lafee, Scott" <slafee@ucsd.edu>
CC: "Carr, Jacqueline" <jcarr@ucsd.edu>

Good morning Scott,

Sorry to darken your doorway on a Monday, but we were just CC'd on a whistleblower letter sent to officials within UCSD and UCOP alleging a number of problems within UCSD's Human Research Protection Program. I'll attach the letter in case you haven't seen it yet.

We have reached out to all the staff at HRPP to get verification that the letter is authentic, and will be reaching out to each person addressed in the complaint for comment, but for now I'm hoping you can help me verify the accuracy of two of the statements made:

1. The whistleblower wrote, "What makes the UCSD HRPP more unique from all other offices of its kind in the UC system is where it is housed. While almost all HRPP offices under the UC system are under the VC for Research and Compliance, the UCSD HRPP is housed under the school of medicine to be overseen by the Director of the UC San Diego Altman Clinical and Translational Research Institute (ACTRI)."

-Is that statement accurate?

-If so, can you work on a comment for us about why that's the case at UCSD? Also, since ACTRI's mission (if I'm reading it correctly) is about helping researchers go from concept through clinical trials, how is that not a conflict of interest if ACTRI is also overseeing the HRPP?

2. The whistleblower wrote that Karen Allen, Regulatory Affairs Director for ACTRI, "started supervising the IRB staff as well. The research staff she supervises are research coordinators who submit study materials to the IRB for review. The research coordinators ultimately work for the investigators. Allen attends and fully participates in the IRB meetings. Allen doesn't leave the room during the IRB meetings when studies her research coordinators have submitted are being deliberated and voted upon. On top of that, Allen reviews, edits, and approves the IRB's letters, which include the studies her staff has submitted."

--Is this statement accurate?

--If so, can you get us a comment about how this dual role does not pose a conflict of interest?

Thanks. Please give me a call if it's easier to talk through any of this.

-Brad

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P.S. We want to hear from you! [Take a brief survey](#) to help us get to know you and the topics you want us to look into.

— Attachments: —

Noncompliance and Human Subject Research Violations Report at
UCSD.pdf

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KB